K123441

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Endoscopy

510(k) SUMMARY, PER 21 CFR 807.92

JAN 09 2013

510(k) Owner/Sponsor:	Stryker Endoscopy
Address:	5900 Optical Court San Jose, CA 95138
Establishment Number:	2936485
Telephone Number:	(408) 754-2701
Contact Person:	Kevin Potgieter, RAC; Senior Regulatory Affairs Analyst
Email Address:	kevin.potgieter@stryker.com
Proposed Device:	Stryker CrossFlow Integrated Arthroscopy Pump
Common/Usual Name:	Arthroscopic Pump, Tubing Sets and Accessories
Product Code:	HRX
FDA Regulation Number:	21 CFR 888.1100 – Arthroscope and accessories
Device Classification:	Class II
Predicate Device:	World of Medicine Arthroscopy Pump A107
Common/Usual Name:	Arthroscopic Pump, Tubing Sets and Accessories
Product Code:	HRX
FDA Regulation Number:	21 CFR 888.1100 - Arthroscope and accessories
Device Classification:	Class II
Premarket Notification:	K030402

Device Description

The Stryker CrossFlow Integrated Arthroscopy Pump is a microprocessor-controlled dual (inflow and outflow) pump system designed to provide liquid distention and irrigation of joint cavities and aspiration of liquids out of the joint cavities during diagnostic and operative arthroscopy. Both the irrigation and aspiration pump of the device function according to the peristaltic principle. The Stryker CrossFlow Integrated Arthroscopy Pump consists of the following main components: console housing, power supply, two peristaltic pumps, three pinch valves, and a touch-screen display panel. The device is to be used with specially designed irrigation and aspiration tube sets and can be operated by remote hand and foot controls. A constantly-performed pressure sensing algorithm controls the value of the actual pressure in the joint cavity as compared to the set pressure determined by the user.

Intended Use/Indications for Use

The Stryker CrossFlow Integrated Arthroscopy Pump is a dual arthroscopic pump system intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow,

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ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.

Technological Comparison

The Stryker CrossFlow Integrated Arthroscopy Pump employs the same technological characteristics as the predicate device. Both devices operate on the peristaltic principle where roller wheels are spun against soft tubing, thus creating flow of fluid within the tubing. One roller wheel controls the inflow (irrigation) side of the pump and the other roller wheel controls the outflow (aspiration) side. Both pumps are controlled by software and microelectronics that execute control algorithms that ensure that the set pressure is being achieved within the patient's joint.

The Stryker CrossFlow Integrated Arthroscopy Pump and the WOM A107 employ different designs in terms of how the tube sets interface with the roller wheels of the pump. The proposed Stryker design utilizes internally-mounted roller wheels that interface with cassettes that are part of the disposable, single-use tube sets. The predicate device uses externally-mounted roller wheels.

The device described in this notification is similar in design and technical characteristics to the predicate device. The differences between the Stryker CrossFlow Integrated Arthroscopy Pump and the WOM A107 Arthroscopy Pump are minor and raise no new questions of safety and effectiveness. Stryker believes that the Stryker CrossFlow Integrated Arthroscopy Pump is substantially equivalent to the predicate device currently on the market.

Performance Testing

The Stryker CrossFlow Integrated Arthroscopy Pump's performance was tested in accordance with design specifications and with voluntary external standards. FDA has not established Recognized Consensus Standards for product code HRX. However the CrossFlow system is designed to conform to the following voluntary safety and performance standards. Biocompatibility was verified per ISO 10993-1:2009/Cor 1:2010 for patient contacting materials. Software was developed, tested, and verified per FDA guidance documents as well as IEC 62304:2006. Electrical Safety is being tested to IEC 60601-1:1988/A1:1991/A2:1995. Electromagnetic Compatibility is verified by testing to and IEC 60601-1-2:2007.

In addition to the above, bench performance testing performed on the Stryker CrossFlow Integrated Arthroscopy Pump verifies that the device satisfies design specifications and their acceptance criteria.

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Conclusion

The submitted information in this premarket notification is complete, and based on the indications for use, technological characteristics, performance testing and comparison to the predicate device, the Stryker CrossFlow Integrated Arthroscopy Pump raises no new questions of safety and effectiveness. The proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stryker, Endosopy
% Underwriters Laboratories, Incorporated
Mr. Jeff Rongero
Senior Project Engineer
12 Laboratory Drive
Research Triangle, North Carolina 27709

Letter dated: January 9, 2013

Re: K123441
Trade/Device Name: Stryker Crossflow Integrated Arthroscopy Pump
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: December 21, 2012
Received: December 31, 2012

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Device Name: Stryker CrossFlow Integrated Arthroscopy Pump

510(k) Number if known: _____

Indications for Use:

The Stryker CrossFlow Integrated Arthroscopy Pump is a dual arthroscopic pump system intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Asundi, PhD
Division of Orthopedic Devices